

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Sunil Chada *et al.*

Serial No.: 10/017,472

Filed: December 7, 2001

For: METHODS OF TREATMENT  
INVOLVING HUMAN MDA-7

Group Art Unit: 1633

Examiner: Li, Qian Janice

Atty. Dkt. No.: INGN:097US

Confirmation No.: 5209

CERTIFICATE OF ELECTRONIC TRANSMISSION  
37 C.F.R. § 1.8

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February 26, 2007  
Date

Travis Wohlers

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

**MS AMENDMENT**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be

construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

A fee as set forth in 37 C.F.R. § 1.17(p) in the amount of \$180.00 is enclosed. If an appropriate payment has not been enclosed, or if it is insufficient, the Commissioner is authorized to deduct the appropriate fee from Fulbright & Jaworski Account No.: 50-1212/INGN:097US.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



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Date: February 26, 2007

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<b>List of Patents and Publications for Applicant's</b>			
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### U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A40	09/615,154	07/13/00	Mhashikar <i>et al.</i>			07/13/00
	A41	2002/0183271	12/05/02	Chada <i>et al.</i>	514	44	12/07/01
	A42	2002/0091098	07/11/02	Fisher	514	44	11/21/01
	A43	2003/0147966	08/07/03	Franzen <i>et al.</i>	424	491	07/10/02
	A44	2003/0223938	12/04/03	Nagy <i>et al.</i>	424	46	04/14/03
	A45	2004/0009939	01/15/04	Chada <i>et al.</i>	514	44	03/03/03
	A46	2005/0101770	05/12/05	Presta	530	388.15	11/09/04
	A47	2005/0143336	06/30/05	Ramesh <i>et al.</i>	514	44	11/30/04
	A48	2006/0134801	06/22/06	Chada <i>et al.</i>	436	177	03/02/04
	A49	5,179,122	01/12/93	Greene <i>et al.</i>	514	458	02/11/91
	A50	5,747,469	05/05/98	Roth <i>et al.</i>	514	44	04/25/94
	A51	6,132,980	10/17/00	Wang <i>et al.</i>	435	7.23	09/28/98
	A52	6,168,791	01/02/01	Larsen <i>et al.</i>	424	158.1	05/21/98
	A53	6,407,218	06/18/02	Tamarkin <i>et al.</i>	530	389.1	11/10/98
	A54	60/661,680	03/14/05	Lin			03/14/05

### Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Language
	B11	WO 00/61626	10/19/00	WIPO	English
	B12	WO 01/60365	08/23/01	WIPO	English
	B13	WO 02/04511	01/17/02	WIPO	English
	B14	WO 02/45737	06/13/02	WIPO	English
	B15	WO 03/075952	09/18/03	WIPO	English

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	B16	WO 03/087308	10/23/03	WIPO	English
	B17	WO 98/16655	04/23/98	WIPO	English
	B18	WO 98/35554	08/20/98	WIPO	English

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	C130	Albert <i>et al.</i> , "Dendritic cell maturation is required for the cross-tolerization of CD8+ T cells," <i>Nat Immunol.</i> , 2(11):1010-1017, 1998.
	C131	Alberts <i>et al.</i> , "Do NSAIDs exert their colon cancer chemoprevention activities through the inhibition of mucosal prostaglandin synthetase," <i>J. Cell. Biochem. Suppl.</i> , 22:18-23, 1995.
	C132	Alshafie <i>et al.</i> , "Chemotherapeutic evaluation of celecoxib, a cyclooxygenase-2 inhibitor, in a rat mammary tumor model," <i>Oncology Reports</i> , 7:1377-1381, 2000.
	C133	Barber, GN., "Host defense, viruses and apoptosis," <i>Cell Death Differ.</i> , 8(2):113-126, 2001.
	C134	Basu <i>et al.</i> , "Cyclooxygenase-2 inhibitor induces apoptosis in breast cancer cells in an <i>in vivo</i> model of spontaneous metastatic breast cancer," <i>Mol. Cancer Res.</i> , 2:632-642, 2004.
	C135	Bedi <i>et al.</i> , "Inhibition of apoptosis during development of colorectal cancer," <i>Cancer Res.</i> , 55(9):1811-1816, 1995.
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	C137	Benoit <i>et al.</i> , "Regulation of HER-2 oncogene expression by cyclooxygenase-2 and prostaglandin E2," <i>Oncogene</i> , 23:1631-1635, 2004.
	C138	Beretta <i>et al.</i> , "Rapamycin blocks the phosphorylation of 4E-BP1 and inhibits cap-dependent initiation of translation," <i>EMBO J.</i> , 15:658-664, 1996.
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	C140	Bonvini <i>et al.</i> , "Geldanamycin abrogates ErbB2 association with proteasome-resistant beta-catenin in melanoma cells, increases beta-catenin-E-cadherin association, and decreases beta-catenin-sensitive transcription," <i>Cancer Res.</i> , 61:1671-1677, 2001.
	C141	Bowie <i>et al.</i> , "Deciphering the message in protein sequences: tolerance to amino acid substitutions," <i>Science</i> , 247(4948):1306-10, 1990
	C142	Chada <i>et al.</i> , "Bystander activity of Ad-mda7: human MDA-7 protein kills melanoma cells via an IL-20 receptor-dependent but STAT3-independent mechanism," <i>Mol. Ther.</i> , 10(6):1085-1095, 2004.
	C143	Chada <i>et al.</i> , "MDA-7/IL-24 is a unique cytokine--tumor suppressor in the IL-10 family," <i>Int. Immunopharmacol.</i> , 4:649-667, 2004.
	C144	Chada <i>et al.</i> , "The multifunctional mda-7 gene encodes both tumor suppressor and TH1 cytokine (IL-24) activities," <i>Cancer Gene Therapy</i> , 10:S3, 2003
	C145	Chattergoon <i>et al.</i> , "Targeted antigen delivery to antigen-presenting cells including dendritic cells by engineered Fas-mediated apoptosis," <i>Nat Biotechnol.</i> , 18(9):974-979, 2000.
	C146	Craven <i>et al.</i> , "A decade of tyrosine kinases: from gene discovery to therapeutics," <i>Surg. Oncol.</i> , 12(1):39-49, 2003.
	C147	Cross <i>et al.</i> , "A p53-dependent mouse spindle checkpoint," <i>Science</i> , 267:1353-1356, 1995.
	C148	Cunningham <i>et al.</i> , "Clinical and local biological effects of an intratumoral injection of mda-7 (IL24; INGN 241) in patients with advanced carcinoma: a phase I study," <i>Molecular Therapy</i> , 11(1):149-159, 2005. (Written in 2003 with Applicant)
	C149	Daigo <i>et al.</i> , "Molecular cloning of a candidate tumor suppressor gene, DLC1, from chromosome 3p21.3," <i>Cancer Research</i> , 59:1966-1972, 1999.
	C150	Database accession No. U70824, GenBank.
	C151	Database accession No. U70880, GenBank.
	C152	Database UniProt, "Interleukin-24 precursor (suppression of tumorigenicity 16 protein) (melanoma differentiation-associated gene 7 protein) (MDA-7)," UniProt accession no.: Q13007, 2004.
	C153	Denkert <i>et al.</i> , "Prognostic impact of cyclooxygenase-2 in breast cancer," <i>Clin. Breast Cancer</i> , 4(6):428-433, 2004.

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	C154	Donze <i>et al.</i> , "The Hsp90 chaperone complex is both a facilitator and a repressor of the dsRNA-dependent kinase PKR," <i>EMBO J.</i> , 20:3771-3780, 2001.
	C155	Dumoutier and Renaud, "Viral and cellular interleukin-10 (IL-10)-related cytokines: from structures to functions," <i>Eur Cytokine News</i> , 13(2):5-15, 2002.
	C156	Earnest <i>et al.</i> , "Piroxicam and other cyclooxygenase inhibitors: potential for cancer chemoprevention," <i>J. Cell Biochem. Suppl.</i> , 161:156-166, 1992.
	C157	El-Rayes <i>et al.</i> , "Cyclooxygenase-2-dependent and -independent effects of celecoxib in pancreatic cancer cell lines," <i>Mol. Cancer Ther.</i> , 3:1421-1426, 2004.
	C158	Fariss <i>et al.</i> , "The selective antiproliferative effects of alpha-tocopheryl hemisuccinate and cholesterol hemisuccinate on murine leukemia cells result from the action of the intact compounds," <i>Cancer Res.</i> , 54:3346-3351, 1994.
	C159	Feng <i>et al.</i> , "Identification of double-stranded RNA-binding domains in the interferon-induced double-stranded RNA-activated p68 kinase," <i>Proc. Natl. Acad. Sci., USA</i> , 89:5447-5451, 1992.
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	C161	Fralcy <i>et al.</i> , "Entrapment of a bacterial plasmid in phospholipid vesicles: potential for gene transfer," <i>Proc. Natl. Acad. Sci. USA</i> , 76:3348-3352, 1979.
	C162	Gale <i>et al.</i> , "Antia apoptotic and oncogenic potentials of hepatitis C virus are linked to interferon resistance by viral repression of the PKR protein kinase," <i>J. Virol.</i> , 73(8):6505-6516, 1999.
	C163	Gale <i>et al.</i> , "Control of PKR protein kinase by hepatitis C virus nonstructural 5A protein: molecular mechanisms of kinase regulation," <i>Mol. Cell Biol.</i> , 18:5208-5218, 1998.
	C164	Gale <i>et al.</i> , "Repression of the PKR protein kinase by the hepatitis C virus NS5A protein: a potential mechanism of interferon resistance," <i>Clinical and Diagnostic Virology</i> , 10:157-162, 1998.
	C165	Gale <i>et al.</i> , "Translational control of viral gene expression in Eukaryotes," <i>Microbiol Mol Biol Rev</i> , 64(2):239-280, 2000.
	C166	Gann <i>et al.</i> , "Low-dose aspirin and incidence of colorectal tumors in a randomized trial," <i>J. Natl. Cancer Inst.</i> , 85:1220-1224, 1993.

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	C167	Garn <i>et al.</i> , "IL-24 is expressed by rat and human macrophages," <i>Immunobiol.</i> , 205:321-334, 2002.
	C168	Garner <i>et al.</i> , "Celecoxib for rheumatoid arthritis," <i>Cochrane Database Syst Rev.</i> , (4):CD003831, 2002. (abstract only)
	C169	Gething and Sambrook, "Protein folding in the cell," <i>Nature</i> , 355(6355):33-45, 1992.
	C170	Giovannucci <i>et al.</i> , "Aspirin use and the risk for colorectal cancer and adenoma in male health professionals," <i>Ann. Intern. Med.</i> , 121:241-246, 1994.
	C171	Giovannucci <i>et al.</i> , "Physical activity, obesity, and risk of colorectal adenoma in women (United States)," <i>Cancer Causes Control</i> , 7(2):253-63, 1996. (abstract only)
	C172	Greenberg <i>et al.</i> , "Reduced risk of large-bowel adenomas among aspirin users. The Polyp Prevention Study Group," <i>J. Natl. Cancer Inst.</i> , 85:912-916, 1993.
	C173	Hanif <i>et al.</i> , "Effects of nonsteroidal anti-inflammatory drugs on proliferation and on induction of apoptosis in colon cancer cells by a prostaglandin-independent path," <i>Biochemical Pharmacology</i> , (52):237 245, 1996.
	C174	Harris <i>et al.</i> , "Chemprevention of breast cancer in rats by celecoxib, a cyclooxygenase 2 inhibitor," <i>Cancer</i> , Abstract Number: 2000-282718, 2000.
	C175	Howe <i>et al.</i> , "Celecoxib, a selective cyclooxygenase 2 inhibitor, protects against human epidermal growth factor receptor 2 (HER-2/neu)-induced breast cancer," <i>Cancer Res.</i> , 62:5405-5407, 2002.
	C176	Howe <i>et al.</i> , "Cyclooxygenase-2: a target for the prevention and treatment of breast cancer," <i>Endocr. Relat. Cancer</i> , 8:97-114, 2001.
	C177	Ji <i>et al.</i> , "Expression of several genes in the human chromosome 3p21.3 homozygous deletion region by an adenovirus vector results in tumor suppressor activities in vitro and in vivo," <i>Cancer Research</i> , 62:2715-2720, 2002
	C178	Judware <i>et al.</i> , "Partial characterization of a cellular factor that regulates the double-stranded RNA-dependent eIF-2 $\alpha$ kinase in 3T3-F442A fibroblasts," <i>Mol. Cell Biol.</i> , 11(6):3259-3267, 1991.
	C179	Kamal <i>et al.</i> , "A high-affinity conformation of Hsp90 confers tumour selectivity on Hsp90 inhibitors," <i>Nature</i> , 425:407-410, 2003.

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	C180	Kaufman, "Orchestrating the unfolded protein response in health and disease," <i>J. Clin Invest.</i> , 110(10):1389-1398, 2002.
	C181	Killary <i>et al.</i> , "Definition of a tumor suppressor locus within human chromosome 3p21-p22," <i>Proc Nat Acad Sci USA</i> , 89:10877-10881, 1992.
	C182	Kismet <i>et al.</i> , "Celecoxib: a potent cyclooxygenase-2 inhibitor in cancer prevention," <i>Cancer Detect Prev.</i> , 28(2):127-42, 2004.
	C183	Kline <i>et al.</i> , "Vitamin E: mechanisms of action as tumor cell growth inhibitors," In: <i>Proceeding of the International Conference on Nutrition and Cancer</i> , Prasad and Cole (Eds.), Amsterdam: IOS Press, 37-53, 1998.
	C184	Kline <i>et al.</i> , "Vitamin E: mechanisms of action as tumor cell growth inhibitors," <i>J. Nutr.</i> , 131: 161S-163S, 2001.
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	C187	Kumar <i>et al.</i> , "Deficient cytokine signaling in mouse embryo fibroblasts with a targeted deletion in the PKR gene: role of IRF-1 and NF- $\kappa$ B," <i>EMBO J.</i> , 16:406-416, 1997.
	C188	Kumar <i>et al.</i> , "Double-stranded RNA-dependent protein kinase activates transcription factor NF- $\kappa$ B by phosphorylating I $\kappa$ B," <i>Proc. Natl. Acad. Sci., USA</i> , 91:6288-6292, 1994.
	C189	Le <i>et al.</i> , "Genes affecting the cell cycle, growth, maintenance, and drug sensitivity are preferentially regulated by anti-HER2 antibody through phosphatidylinositol 3-kinase-AKT signaling," <i>J. Biol. Chem.</i> , 280(3):2092-2104, 2005.
	C190	Lebedeva <i>et al.</i> , "Restoring apoptosis as a strategy for cancer gene therapy: focus on p53 and mda-7," <i>Semin Cancer Biol.</i> , 13(2):169-178, 2003.
	C191	Lenardo <i>et al.</i> , "The involvement of NF- $\kappa$ B in $\beta$ -interferon gene regulation reveals its role as widely inducible mediator of signal transduction," <i>Cell</i> , 57:287-294, 1989.

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	C192	Leng <i>et al.</i> , "Cyclooxygenase-2 promotes hepatocellular carcinoma cell growth through Akt activation: evidence for Akt inhibition in celecoxib-induced apoptosis," <i>Hepatology</i> , 38:756-768, 2003.
	C193	Lerman <i>et al.</i> , "The 630-kb lung cancer homozygous deletion region on human chromosome 3p21.3: identification and evaluation of the resident candidate tumor suppressor genes. The International Lung Cancer Chromosome 3p21.3 Tumor Suppressor Gene Consortium," <i>Cancer Research</i> , 60:6116-6133, 2000.
	C194	Liu <i>et al.</i> , "Combination of radiation and celebrex (celecoxib) reduce mammary and lung tumor growth," <i>Am. J. Clin. Oncol.</i> , 26:S103-109, 2003.
	C195	Lupulescu, "Control of precursor cell transformation into cancer cells: its relevance to cancer prevention," <i>Cancer Detect. Prev.</i> , 20(6):634-637, 1996.
	C196	Malafa and Neitzel, "Vitamin E succinate promotes breast cancer tumor dormancy," <i>J. Surg. Res.</i> , 93:163-170, 2000.
	C197	Malafa <i>et al.</i> , "Vitamin E inhibits melanoma growth in mice," <i>Surgery</i> , 131:85-91, 2002.
	C198	Maloney and Workman, "HSP90 as a new therapeutic target for cancer therapy: the story unfolds," <i>Expert Opin. Biol. Ther.</i> , 2:3-24, 2002. (abstract only)
	C199	Mandler <i>et al.</i> , "Modifications in synthesis strategy improve the yield and efficacy of geldanamycin-herceptin immunoconjugates," <i>Bioconjug. Chem.</i> , 13(4):786-791, 2002.
	C200	Maniotis <i>et al.</i> , "Vascular Channel Formation by Human Melanoma Cells In Vivo and In Vitro: Vasculogenic Mimicry," <i>Am. J. Pathology</i> , 155:739-752, 1999.
	C201	Maran <i>et al.</i> , "Blockage of NF- $\kappa$ B signalling by selective ablation of an mRNA target by 2-5A antisense chimeras," <i>Science</i> , 265:789-792, 1994.
	C202	McKenzie <i>et al.</i> , "Combination therapy of Ad-mda7 and trastuzumab increases cell death in Her-2/neu-overexpressing breast cancer cells," <i>Surgery</i> , 136:437-442, 2004.
	C203	Merrick and Hershey, "The pathway and mechanism of eukaryotic protein synthesis," In: <i>Translational Control</i> , Hershey <i>et al.</i> , (Eds.), Cold Spring Harbor Laboratory Press, NY, 31-69, 1996.
	C204	Meurs <i>et al.</i> , "Molecular cloning and characterization of the human double-stranded RNA-activated protein kinases induced by interferon," <i>Cell</i> , 62:379-390, 1990.

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	C205	Meurs <i>et al.</i> , "Tumor suppressor function of the interferon-induced double-stranded RNA-activated protein kinase," <i>Proc. Natl. Acad. Sci., USA</i> , 90:232-236, 1993.
	C206	Mhashikar <i>et al.</i> , "MDA-7 negatively regulates the beta-catenin and PI3K signaling pathways in breast and lung tumor cells," <i>Mol. Ther.</i> , 8:207-219, 2003.
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